Practitioner's Docket No. <u>U 015859-4</u>

CHAPTER II

IN THE UNITED STATES ELECTED OFFICE (EO/US)

PCT/ES2004/070001 21 JANUARY 2004 28 JANUARY 2003, ETC.
INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED

METHOD AND DEVICE FOR THE DETECTIVE OF MUTATIONS,
PERCHOLESTROLEMIA

TITLE OF INVENTION

PEDRO MATA LOPEZ, ET AL.

Mail Stop PCT Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450 ATTENTION: EO/US

APPLICANT(S)

COMPLETION OF FILING REQUIREMENTS FOR INTERNATIONAL APPLICATION ENTERING U.S. NATIONAL STAGE IN U.S. ELECTED OFFICE (EO/US) UNDER 35 U.S.C. § 371

(check and complete the applicable item, if applicable)

[X] This replies to the Notice of Missing Requirements under 35 U.S.C. § 371 and 37 C.F.R. § 1.495 (FORM PCT/DO/EO/905).

[X] A copy of FORM PCT/DO/EO/905 accompanies this response.

CERTIFICATION UNDER 37 C.F.R. 1.10*

(Express Mail label number is mandatory.)
(Express Mail certification is optional.)

I hereby certify that this Completion of Filing Requirements and the papers indicated as being transmitted therewith are being deposited with the United States Postal Service on this date <u>September 8, 2006</u>, in an envelope as "Express Mail Post Office to Addressee," Mailing Label Number <u>EV815585795US</u>, addressed to the: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Geraldine Marti

type or print name of person mailing paper)

Signature of person mailing paper

WARNING:

Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

*WARNING:

Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).

"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

WARNING:

Where the items being submitted to complete the entry of the international application into the national phase are subsequent to 30 months from the priority date the application is still considered to be in the international state and if mailing procedures are utilized to obtain a date the express mail procedure of 37 C.F.R. § 1.10 must be used (because international application papers are not covered by an ordinary certificate of mailing. 37 C.F.R. § 108(2)(xi).

NOTE:

Documents and fees must be clearly identified as a submission to enter the national stage under 35 U.S.C. § 371. Otherwise, the submission will be considered as being made under 35 U.S.C. § 111. 37 C.F.R. § 1.495(g).

DECLARATION OR OATH

NOTE: 37 C.F.R. § 1.495(c): "If applicant complies with paragraph (b) of this section before expiration of thirty months from the priority date but omits... the oath or declaration of the inventor (35 U.S.C. 371(c)(4) and § 1.497), if a declaration of inventorship in compliance with § 1.497 has not been previously submitted in the international application under PCT Rule 4.17 (iv) within the time limits provided for in PCT Rule 26ter.1, applicant will be so notified and given a period of time within which to file the ... oath or declaration in order to prevent abandonment of the application The payment of the surcharge set forth in § 1.492(e) is required for acceptance of the oath or declaration of the inventor later than the expiration of thirty months after the priority date."

I. (a) [x] No original declaration or oath was filed. Enclosed is the original declaration or oath for this application.

OR

(b) [] The declaration or oath that was filed was determined to be defective. A new original oath or declaration is attached.

NOTE: For surcharge fee for filing declaration after filing date complete item IV(3)

NOTE:

- NOTE: Acceptable minimums in the declaration in an ordinarily filed U.S. application for identification of the specification to which it applies are:
- (A) application number (consisting of the series code and the serial number, e.g., 08/123,456);
- (B) serial number and filing date;
- (C) attorney docket number which was on the specification as filed;
- (D) title which was on the specification as filed and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration; or
- (E) title which was on the specification as filed and accompanied by a cover letter accurately identifying the application for which it was intended by either the application number (consisting of the series code and the serial number, e.g., 08/123,456), or serial number and filing date. Absent any statement(s) to the contrary, it will be presumed that the application filed in the PTO is the application which the inventor(s) executed by signing the oath or declaration.

M.P.E.P. § 602, 8th ed.

NOTE:

Another minimum found acceptable in the declaration is the filing date (i.e., date of express mail) and the express mail number, useful where the serial number is not yet known. But note the practice where the express mail deposit is a Saturday, Sunday or holiday within the District of Columbia. 37 C.F.R. § 1.10(c).

NOTE:

See 37 C.F.R. § 1.41(a).

(complete as applicable)

	Attach	ed is a				
	(a) [] Statement by practitioner that papers attached to declaration are a those filed in PTO to get a filing date					
	(b) [] Statement that substitute specification contains no new matter.					
	(c)	[*]	Preliminary Amendment			
	(d) [x] Submission of "Sequence Listing," computer readable copy, and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence					
			TRANSMITTAL OF ENGLISH TRANSLATION OF NON-ENGLISH LANGUAGE PAPERS			
II.	[]	Submitted herewith is an English translation of the non-English language international application papers as originally filed. It is requested that this translation be used as the copy for examination purposes in the PTO. (See 37 C.F.R. 1.495(c))				
NOTE:		For fee for processing a non-English application, complete item $IV(4)$.				
NOTE:		A non-English oath or declaration in the form provided or approved by the PTO need not be translated. 37 C.F.R. § 1.69(b).				
III.			FEES			
	: See 37 C	C.F.R. § 1	28(a).			
1.	Fees fo	or search	ı, exam or claims			
	[]		.S. Search Report filed —\$400.00; entity—\$200.00	\$		
	[]	No Sea	arch Report —\$500.00; small entity —\$250.00	\$		
	[]	Exam 1	Fee not paid to U. S—\$200.00; small entity—\$100.00	\$		
	[]		and Exam fee with U.S. WO or IPER conditions isfied—\$100.00; small entity—\$50.00	\$		
	[]		and Exam fee with U.S. WO or IPER conditions ed—\$0.00	\$		

	(]	Spec and of 37 C.F.R.	drawing 1.16(s)	g, each 50 pages over 100)—\$250.00	\$		
	1	[]	Each inde (37 C.F.R	penden	nt claim in excess of 3 92—\$200.00; small entity—\$100.00	\$		
	·	[]	each clair (37 C.F.R	n in ex	cess of 20 92—\$50.00; small entity—\$25.00	\$		
		[x]	multiple (37 C.F.F	depend R. § 1.4	lent claims(s) 192—\$360.00; small entity—\$180.00	\$ <u>360.00</u>		
2		Surcha	rge fees					
		[x]	the decla	ration l an appl	orth in 37 C.F.R. § 1.492(e) for accepting later than 30 months after the priority date lication in the U.S. as a designated 0; small entity—\$65.00	\$	130.00	
NOTE: The processing fee in the next item 3 below is not subject to a reduction for small entity status.								
3	3.	[]	for acce	ntance	set forth in 37 C.F.R. § 1.492(f) of an English translation later s after the priority date—\$130.00	\$		
					Total Fees	\$		
					SMALL ENTITY STATUS			
	IV.	a.	[]	A State	ement or Written Assertion that this filing is	by a small	entity	
		NOTE	: See 37 C.	F.R. § 1.	.28(a).		-	
					(check and complete applicable items)			
				[] [] []	is attached. was filed on was made by paying the basic national fee	e as a small	entity.	
		b.	[]	A sep	parate refund request accompanies this paper			
09/12/2006 H	KAYPAGI	1 000001	03 10542937					
01 FC:1616 02 FC:1617			360	.00 OP				

EXTENSION OF TIME

(complete (a) or (b), as applicable)

	V. The proceedings herein are for a patent application. Accordingly, the provisions of 37 C. 1.136(a) apply.								F.R.
				-				or which are set ou ths checked out be	
			Extension (months)		or other than nall entity		<u>s</u>	Fee for mall entity	
		[]	one month	\$	120.00			\$ 60.00	
		[]	two months	.\$	450.00		;	\$ 225.00	
		[]	three months	\$	1,020.00		:	\$ 510.00	
		[x]	four months	\$	1,590.00		;	\$ 795.00	
		NOTE:	the Notice as a statu	tory period subjec llowed by additio	ct to 35 U.S.C. 13	3. Thus, extensi	ons of tir	ication is not identified me of up to 5 months un ppropriate, are permiti	der
		[]	five months	\$	2,160.00			\$ 1,080.00	
						Fee:	\$_	1,590.00	
		If an ad	ditional extensior	of time is rec	quired, please	consider thi	is a pet	ition therefor.	
			(check	and complete	the next item	, if applicab	le)		
		[]	An extension for of \$extension now re	is deduct	nonths has air ed from the to	ready been so otal fee due	ecured for the	The fee paid ther total months of	efor
			Extension fee du	e with this rec	uest \$				
					or				
	(b)	[]		made to provi	de for the pos	sibility that	applica	ver, this condition ant has inadvertence.	
09/12/2006 M	KAYPAGH	00000103 10)542937						
03 FC:1254			1590.00 OP						
						-			

TOTAL FEE DUE

VI.

The total fee due is:

PAYMENT OF FEES

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v	1	u	L

[x]	Enclosed is a check in the amount of \$2,080.00
[]	Charge Account No. 12-0425 in the amount of \$
[]	A duplicate of this request is attached.

NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 C.F.R. § 1.22(b).

AUTHORIZATION TO CHARGE ADDITIONAL FEES

VIII.

WARNING:

Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges if extra claims are authorized.

NOTE:

"A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3).

NOTE:

"Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).

- [X] The Commissioner is hereby authorized to charge the following additional fees that may be required by this paper and during the entire pendency of this application to Account No. 12-0425
 - [X] 37 C.F.R. § 1.492(a), (b) or (c) (search or exam fee)

[x] 37 C.F.R. § 1.492(b), (c), and (d) (presentation of extra claims)

NOTE:

Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. \S 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

- [X] 37 C.F.R. 1.16(s) (spec and drawing, each 50 pages over 100)
- [X] 37 C.F.R. § 1.17 (application processing fees)
- [X] 37 C.F.R. \S 1.17(a)(1)-(5) (extension fees pursuant to \S 1.136(a)).

Section 1.311(b) provides that an authorization to charge the issue fee (§ 1.18) to a deposit account may be filed in an individual application only after the mailing of the notice of allowance. Accordingly, general authorizations to any fees and specific authorizations to pay the issue fee that are filed prior to the mailing of a notice of allowance will generally not be treated as requesting payment of the issue fee and will not be given effect to act as a reply to the notice of allowance. Applicant, when paying the issue fee, should submit a new authorization to charge fees, such as by completing box 6b on the current PTOL 85-B form. Where no reply to the notice of allowance is received, the application will stand abandoned notwithstanding the presence of general authorizations to pay fees or a specific authorization to pay the issue fee that were submitted prior to mailing of the notice of allowance. Where an attempt is made to pay the issue fee but an incorrect amount is submitted, § 1,311(b)(1), or where the Office's issue fee transmittal form (currently PTOL-85(B)) is completed by applicant ans submitted, § 1.311 (b)(2), in reply to a notice of allowance, an exception will be made. Such submissions will operate as a request to charge the issue fee to any deposit account identified in a previously filed (i.e., submitted prior to the mailing of the notice of allowance) authorization to charge fees, and will be allowed to act as payment of the correct issue fee. § 1.311(b). See also the change to § 1.26(b), Notice of September 8, 2000, Fed. Reg. 54603-54683, at 54646 and 54647.

[X] 37 C.F.R. § 1.492(e) and/or (f) surcharge fees for filing the declaration and/or an English translation of an international application later than 30 months from the earliest-claimed priority date.

WARNING:

It would be wise to always check this last authorization.

Refund any overpayment to deposit account 12-0425.

IGNATURE OF PRACTITIONER

Reg. No.: 33,778

Tel. No.: (212) 708-1935

Janet I. Cord

(type or print name of practitioner)

P.O. Address

c/o Ladas & Parry LLP 26 West 61st Street New York, N.Y. 10023

Customer No.:

00140

PATENT TRADEMARK OFFICE



140

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS FO. Box 1450 Alexandra, Vriginia 22313-1450 www.uspto.gov

U.S. APPLICATION NUMBER NO. FIRST NAMED APPLICANT ATTY. DOCKET NO. 10/542,937

Pedro Mata Lopez

U 015859-4

LADAS & PARRY

RECEIVED MAR 2 0 2006 L&PLLP

INTERNATIONAL APPLICATION NO. PCT/ES04/70001 I.A. FILING DATE PRIORITY DATE 01/21/2004 01/28/2003

CONFIRMATION NO. 5381 371 FORMALITIES LETTER *OC000000018206333*

Date Mailed: 03/09/2006

26 WEST 61ST STREET NEW YORK, NY 10023

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 07/21/2005
- Copy of the International Search Report filed on 07/21/2005
- Copy of IPE Report filed on 07/21/2005
- Copy of Annexes to the IPER filed on 07/21/2005
- Biochemical Sequence Diskette filed on 07/21/2005
- Biochemical Sequence Listing filed on 07/21/2005
- U.S. Basic National Fees filed on 07/21/2005
- Specification filed on 07/21/2005
- Claims filed on 07/21/2005
- Abstracts filed on 07/21/2005
 - Drawings filed on 07/21/2005

The applicant needs to satisfy supplemental fees problems indicated below.

The following items MUST be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Additional claim fees of \$360 as a non-small entity, including any required multiple dependent claim fee. are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- Oath or declaration of the inventors, in:compliance with 37 CFR 1.497(a) and (b), identifying the application. by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath



or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fees required for this application is \$490 for a Large Entity:

- \$130 Surcharge.
 - A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of
 the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as
 indicated on the attached copy of the marked -up "Raw Sequence Listing." Applicant must provide a
 substitute computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content
 of the sequence listing information recorded in computer readable form is identical to the written (on paper
 or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR
 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d).
- Total additional claim fee(s) for this application is \$ 360
 - \$360 for multiple dependent claim surchare.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

A copy of this notice MUST be returned with the response.

PATRICIA A BOOKER

Telephone: (703) 308-9140 EXT 204

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/542.937	PCT/ES04/70001	U 015859-4

FORM PCT/DO/EO/905 (371 Formalities Notice)

Mail Stop PCT **Commissioner for Patents** P. O. Box 1450 Alexandria, VA 22313-1450

ATTENTION: EO/US

CERTIFICATION UNDER 37 C.F.R. 1.10*

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(type or print name of person mailing paper)

Signature of person mailing paper

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